



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

OCT 10 1997

Mr. Ian Hicks  
President  
Bio-Sphere Technology  
Research and Development Office  
17991 Fitch  
Irvine, California 92614

0779 '97 DEC 16 P1:39

Dear Mr. Hicks:

This is in response to your letter of January 22, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Bio-Sphere Technology is making the following claims, among others, for "CHOL-LESS-TEROL:"

Lowers Cholesterol  
Reduce serum LDL cholesterol levels  
The National Institute of Health states that for those with high blood cholesterol, lowering your cholesterol level can reduce your risk of a heart attack

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat or prevent diseases, namely, hypercholesterolemia and heart disease. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

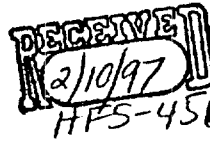
James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 76

BIO-SHIELD  
TECHNOLOGY

January 22, 1997



0780 '97 DEC 16 P1:39

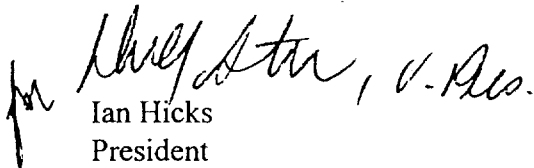
James Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Department of Health & Human Services (HFS-456)  
Food and Drug Administration  
200 C Street Southwest  
Washington, DC 20204

Dear Dr. Tanner,

Thank you for your letter of January 9, 1997 again. We are submitting this latest modification of our proposed cholesterol statement in lieu of our proposed statement regarding LDL-Lite suggested to you in my letter of January 17, 1997 to you.

Your assistance in this matter is appreciated.

Yours sincerely,

  
Ian Hicks  
President

enc.: Submit copy of Cho Less terol label corrected 1/22/97 to FDA

cc: Center for Drug Evaluation and research  
Office of Compliance  
HFD-310  
7520 Standish Place  
Rockville, Maryland 20855

STED USE: As a dietary supplement, orally,  
 4 with full glass of water 30 minutes prior to  
 ree daily meals, or as directed by a health  
 nol.

TAKE MORE THAN 6 TABLETS DAILY.  
 FULL GLASSES OF WATER DAILY.  
 dent clinical studies have indicated that  
 sterol and Pectin, in conjunction with a  
 take program, have been shown to reduce  
 cholesterol levels by up to 7.6%. Penning-  
 ton, Texas, CA.

sterol-Pectin Complex, January 1996. The  
 Institute of Health states that for those with  
 xid cholesterol, lowering your cholesterol level  
 ce your risk of a heart attack.

ING: PLEASE CONSULT YOUR HEALTH PRO-  
 FICATOR PRIOR TO STARTING ANY NUTRITION-  
 IFICATION PROGRAM OR IF YOU HAVE A  
 E OR HEALTH RELATED PROGRAM REQUIR-  
 WERNG YOUR CHOLESTEROL LEVELS. NOT  
 MENDED FOR PREGNANT OR LACTATING

ANT: KEEP OUT OF REACH OF CHILDREN. IF  
 SEAL IS BROKEN OR MISSING, DO NOT

ONS OR COMMENTS? Please Call  
 1-800-8353, 10:00 A.M. to 4:00 P.M., C.S.T.,  
 thru Friday.

WILLIAMS GROUP INTERNATIONAL

# CHO LESS TEROL

LOWERS CHOLESTEROL

DIETARY SUPPLEMENT 48 TABLETS

## Nutrition Facts

Serving Size 1 Tablet

Servings Per Container 48

Amount Per Serving	%Daily Value
Beta-Sterol 300mg	*
Pectin 30mg	*

\*Daily Value not established

CHO-LESS-TEROL does not contain artificial  
 coloring, artificial flavors, sugar, preservatives,  
 petroleum based products, dyes, yeast, wheat or  
 corn flour, starch, or milk products.

Independent clinical studies have shown that the  
 use of beta-sterol-pectin complex tablets  
 adjusts cholesterol to more normal levels by  
 reducing dietary fat and cholesterol absorption  
 from the foods we eat.

\*\*This statement has not been evaluated by the  
 Food and Drug Administration. This product is  
 not intended to diagnose, treat, cure or prevent  
 any disease.

Formulated by  
 Williams Group International, Inc.  
 Guthrie, OK 73044



Your job will be executed in the color combination and design  
 specified on our proof.

PLEASE CHECK THIS PROOF IMMEDIATELY FOR APPROVAL  
 OR CORRECTIONS.

If the proof is correct as submitted, it should be initialed and dated. If  
 corrections are necessary, they should be clearly indicated in the appropriate  
 areas. We make every effort to submit proofs which follow the instructions  
 furnished to us, but we cannot assume responsibility for errors or omissions  
 that customers do not correct.

This job will be executed based on this proof, so I urge you to give this proof  
 immediate and careful attention. You are held accountable.

Thank you for placing your order with us.

Approved as is \_\_\_\_\_ Approved with changes \_\_\_\_\_

*1-22-97 delete this and  
 add... and dietary fat absorption.  
 Biosphere Technology  
 Reno, Nevada  
 should not be  
 placed on a  
 label*

*1-15-97  
 Please review & add  
 comments  
 Wm*

## PERSHING PRODUCTS

17 Jan. 1997

James Tanner, Ph.D.  
Acting Director,  
Division of Programs and Enforcement Policy  
Department of Health & Human Services (HFS-456)  
Food and Drug Administration  
200 C Street SW  
Washington DC 20204

0781 '97 DEC 16 P1:39

Dear Dr. Tanner:

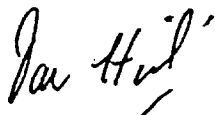
Thank you for your letter of January 9, 1997 concerning our statement regarding LDL-Lite. The product will actually be marketed with a booklet of recommended dietary management. We would therefore ask that if this fact is highlighted more prominently, along with the removal of the heart symbol, would the labeling then be acceptable according to the relevant section of the act.

We propose the change to the following:

"In conjunction with proper dietary management, you may reduce your cholesterol up to 15% in 4 weeks."

Please be advised that we are going to change the name of the company - actually do away with Pershing Products and revert to operating under the name of BioSphere technology, which is the parent company.

Yours sincerely,



Ian Hicks  
President